

Mary Davis Roberts

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(Letter via fax, 3-22-99)

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March 22, 1999

Elizabeth Hiner, R.Ph.
Dockets Management Branch (HFA-305)
Docket No. 98-N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Docket No
98-N-1265

Dear Ms. Hiner:

Late last week, I was horrified to learn of the DRAFT M.O.U. being proposed by the FDA! In particular, I object to the definition of "inordinate amount" which restricts the availability and the right to obtain medically-necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

Ms. Hiner, I'm sure you're a very busy person so I will spare you a lengthy letter detailing my personal medical history. However, as the result of a hysterectomy/oophorectomy at the age of 37, I spent literally seven years out of my life in pure hell, physically and mentally, trying no less than 6-8 different "FDA-approved" hormone replacement therapies. I don't even remember how many gynecologists I saw during this time...but every time my hormone levels were measured, it was obvious (to them) that my body wasn't properly processing/using the recommended HRT. (Of course I knew this prior to testing based on how I felt! I was, quite literally, unable to work, on a full-time basis, during this entire time!) I even underwent a surgical subcutaneous hormone implant procedure - twice - (which lasted only a few weeks, not 4-6 months, as it does in most patients) in order to find relief! I was desperate for an answer, a return of my good health, and I was pretty much willing to try whatever the "newest" doctor recommended.

Thank goodness, I became so completely frustrated with "conventional" medical advice that I finally began several long years of intense research and reading. That research led me to what's been successfully working for me (for a full year now): compounded sublingual HRT tablets that I order, BY PRESCRIPTION, according to what works for ME, from College Pharmacy in Colorado Springs. Ms. Hiner, Pete Huescman, R.Ph., P.D., College Pharmacy's HRT Consultant Pharmacist Specialist, quite literally saved my sanity. In fact, several months ago, my husband said (and I AM quoting), "If I had \$10,000 to send to Pete, I'd do it in a minute. I can't believe the difference this has made."

Yes, the improvement in my health has been "that dramatic." (And, should you doubt me, you can call my Gynecology Specialist, Evelyn Carver Kikta, R.N.C., A.R.N.P., at The Center for Human Reproduction, 727-796-7705. She, too, was amazed at the difference the compounded HRT made in my health and overall appearance. I don't think I'm being melodramatic to say I was probably close to suicide after years and years of being patted on the head (once literally!) and asked, "Umm...have you ever thought about seeing a psychologist?" That seemed to be their standard answer when my

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body didn't respond to the "usual" run of hormone replacement therapy drugs. Even though I got used to hearing that, when the practitioner had exhausted all his/her bag of tricks, though, I never accepted it as an answer. In fact, it just served as the continuing impetus behind more reading and research on my part! I KNEW my problems were caused by a chemical (i.e., hormonal) imbalance because everything I was experiencing was physical and fell right under the long, long lists of problems associated with surgical menopause!

I would assume that this proposal is probably coming from the "one size fits all" pharmaceutical companies who are starting to realize that more and more women are taking responsibility for our health...rather than continuing to allow drug reps to determine what we do or don't put into our bodies. Just a hunch...but I bet I'm close, if not right on. In fact, I pay particular attention to the advertising/marketing efforts of pharmaceutical companies. After YEARS of not seeing anything promoting the "benefits" of Premarin, I've noticed that they are now running full-page print ads. In fact, I believe they are trying to recapture lost prescription sales by telling us how we should stay with the company (i.e., the drug) with the longest history of research and testing. Well, I'd be the very FIRST to tell a Premarin rep that Premarin not only didn't help me...it made me worse. MUCH worse. (But I continued to take it for over four years...because it was the only option offered to me at the time. Women today DO have options when it comes to HRT...and most of us are intelligent enough to want to learn all we can.)

I'm not sure how to "end" this letter. If I thought my one voice/experience would truly make a difference, I could spend hours...and write volumes for you...including sharing my personal experience in detail AND providing you with research information I've garnered. At this time, however, I'll end with a plea. My (previous) gynecologist said I needed a hysterectomy/oophorectomy because I suffered from severe endometriosis. For over fifteen years. I was in tremendous, increasingly worse pain...so I finally agreed to have the surgery (TAH/BSO). I trusted my doctor, I didn't research the possible repercussions, and today I deeply regret the surgery. I've suffered horribly at the hands of way too many misinformed gynecologists for far too many years.

But, Ms. Hiner, I finally found a hormone replacement therapy that my body accepts as "normal." (I can even work full-time once again.) Please do anything you can to stop this bill from becoming an unthinkable reality for thousands of people. I beg of you.

Sincerely,



Mary Roberts

cc: Evelyn Carver Kikta, R.N.C., A.R.N.P. – The Center for Human Reproduction
Pete Hueseman, R.Ph., P.D. – College Pharmacy



WOMEN'S HEALTH
A M E R I C A™
Group

Providing Knowledge, Hope and Help to Women

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America, Inc.**

**A Specialized
Women's Pharmacy**

**National Women's
Health Hotline
PMS Access**

Who We Are

**Online Ordering
& Rx Refills**

Great Connections

Women's News

**Women's Health
Library**

Info Log

Membership

Talk to Us

**Women's Health
Access Newsletter**

Meet Our Staff

URGENT.....URGENT..... URGENT..... URGENT..... URGENT

Dear Friend:

I'm writing to you because the Food and Drug Administration is trying to take away the choices you have about your medications!

For 20 years, Madison Pharmacy Associates has specialized in compounding medications for women experiencing infertility, premenstrual syndrome, and for those taking natural HRT during perimenopause and menopause. We work closely with patients and providers to determine which hormones a woman requires, the best form for her, and the right amount based on her individual needs. Our prescriptions are carefully formulated and shipped from our specialized pharmacy in Wisconsin to individual women throughout America who need our unique service.

The FDA is trying to limit ALL specialized pharmacies, including our pharmacy, Madison Pharmacy Associates, and curtail your choices, through legislation that will restrict the ability to ship compounded prescription medications for personal use across state lines.

DON'T LET LOBBYISTS DECIDE FOR YOU

What's behind the effort to keep us from sending prescriptions outside the state of Wisconsin? It's very simple. Large pharmaceutical companies, armed with millions of dollars and powerful lobbyists. All of a sudden, these mega-corporations want to capture a market they didn't much care about when we started 20 years ago. Back then, Madison Pharmacy Associates, the first women's health pharmacy in the nation, offered information, individually compounded medications, and support to women when they had nowhere else to turn.

Times have changed, and the large drug companies are just now realizing that the approach we have taken for 20 years is the right one. It's just now dawning on them that "one size fits all" medicine, which has been their standard M.O. for decades, is NOT what consumers and health providers want. So they're trying to recapture these lost prescription sales and take complete control of the enormous, growing market of women who need and use individualized, compounded prescriptions.

To corner the market, the huge corporations want to surround and devour us, and they're using the FDA as their vehicle to do so. With pharmacies like ours out of the way, your medication choices will be limited to only those drugs commercially manufactured for the mass "one size fits all" market by large drug companies — no more individually compounded medicines based on your unique needs.

The FDA is circulating a **memorandum of understanding (MOU)** to state boards of pharmacy all over the country. If this document is adopted by these state boards, you'll no longer be able to get the medication you need from us because we won't be able to ship to other states.

MAKE YOUR VOICES HEARD

The FDA is required to ask for public comments on the MOU, and that's where I need your help. Please take a moment **today** to send your comments to the FDA — Docket No. 98N-1265. I can't stress the urgency enough — unless the FDA receives enough public comments by **March 22** indicating that the public **does not support** restricting the availability of individually compounded medications, the MOU will be adopted. **That will mean that government, not you and your doctor, will have decided what's best for you.**

When you write to the FDA in the envelope provided, you may want to make these points:

- Explain how you have used a compounded medication, and how it has made a difference in your life and health.
- Of course, you'll want to express yourself in your own words, but you may want to include statements like these:

My compounded prescription relieves my symptoms and makes it possible for me to live normally throughout the month.

I have used compounded natural hormones to protect against miscarriage.

My compounded medication alleviates symptoms that were previously debilitating, such as depression, sleeplessness, and difficulty concentrating.

In your letter to the FDA, **voice your objection** to the definition of "inordinate amount" contained in the MOU. By "inordinate amount", the FDA means that only a limited number prescriptions could be shipped out of state by a specialized pharmacy. **State your concern** that this limitation would compromise your quality of life by restricting your ability to obtain medication your doctor has prescribed and that you need.

Explain, in your own words, that the services specialty pharmacies provide to you and your doctor are not available from commercial pharmaceutical manufacturers, nor most local pharmacies.

We value our relationship with you, and want to continue to provide service to women who need it, **regardless of where they live, and without government intervention.** Thank you for helping us stand up

for your right to choose where and how you get the medication you need.

If you have any questions, please call me at 1-800-558-7046, ext. 101.

Sincerely,

Marla Ahlgrimm, R.Ph.

President and Founder

PS: Be sure to send your comments to Elizabeth Hiner, R.Ph., at the FDA **before March 22** using the sample letter shown at the bottom of this page. You can also fax your letter to Ms. Hiner at 301-443-2143. If you would prefer to contact her directly by email, you can do so at bhiner@ora.fda.gov

TO WRITE YOUR REPRESENTATIVES IN CONGRESS and voice your objection to the proposed FDA regulations, please [CLICK HERE](#).

Sample Letter

Elizabeth Hiner, R.Ph.
Dockets Management Branch (HFA-305)
Docket No. 98-N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

I OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular, I OBJECT to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

Signature

Date

COMMENTS: _____

1-800-222-4767

National Women's Hotline

Help Desk Status Report

User's Name	Task Name	BIOS Ver	ClkSpd	Y2k Test Comple	PASS/FAIL	Scheduled Start	Scheduled Finish	Resource Names
Elisee Murphy	y2kptest					Mon 3/22/99 10:30 AM	Mon 3/22/99 11:15 AM	Kevin Williams
Patsy Nyman	y2kptest					Mon 3/22/99 11:15 AM	Mon 3/22/99 12:00 PM	Thomas Brooks
Lori Pisciotto	y2kptest					Mon 3/22/99 11:15 AM	Mon 3/22/99 12:00 PM	Jennifer Brown
Donna Porter	y2kptest					Mon 3/22/99 11:15 AM	Mon 3/22/99 12:00 PM	Kevin Williams
George Salem	y2kptest					Mon 3/22/99 1:00 PM	Mon 3/22/99 1:45 PM	Thomas Brooks
Leonard Valenti	y2kptest					Mon 3/22/99 1:00 PM	Mon 3/22/99 1:45 PM	Jennifer Brown
James Yager	y2kptest					Mon 3/22/99 1:00 PM	Mon 3/22/99 1:45 PM	Kevin Williams
Detail in DFS	y2kptest					Mon 3/22/99 1:45 PM	Mon 3/22/99 2:30 PM	Thomas Brooks
DFSR SUMMARY	DFSR SUMMARY					Mon 3/22/99 1:45 PM	Mon 3/22/99 2:30 PM	Jennifer Brown
Randal Arbaugh	y2kptest	Compag FC-01-00	267	3/23/99	PASS	Mon 3/22/99 1:45 PM	Mon 3/22/99 2:30 PM	Kevin Williams
Richard Barnes	y2kptest	Compag FC-01-00	267	3/22/99	PASS	Mon 3/22/99 2:30 PM	Mon 3/22/99 3:15 PM	Thomas Brooks
Robert Brands	y2kptest	Compag FC-01-00	267	3/23/99	PASS	Mon 3/22/99 2:30 PM	Mon 3/22/99 3:15 PM	Jennifer Brown
Max Gastile	y2kptest					Mon 3/22/99 2:30 PM	Mon 3/22/99 3:15 PM	Kevin Williams
Lena Dodley	y2kptest	Compag FC-01-00	267	3/23/99	PASS	Mon 3/22/99 3:15 PM	Mon 3/22/99 4:00 PM	Thomas Brooks
Betty Dodson	y2kptest	Compag FC-01-00	267	3/23/99	PASS	Mon 3/22/99 3:15 PM	Mon 3/22/99 4:00 PM	Jennifer Brown
Leonard Genova	y2kptest	Compag FC-01-00	267	3/22/99	PASS	Mon 3/22/99 3:15 PM	Mon 3/22/99 4:00 PM	Kevin Williams
Kassandra Griffith-Harvey	y2kptest	Compag FC-01-00	267	3/23/99	PASS	Mon 3/22/99 4:00 PM	Mon 3/22/99 4:45 PM	Thomas Brooks
Betty Hiner	y2kptest	Compag FC-01-00	267	3/23/99	PASS	Mon 3/22/99 4:00 PM	Mon 3/22/99 4:45 PM	Jennifer Brown
Glenn Johnson	y2kptest	Compag FC-01-00	267	3/23/99	PASS	Mon 3/22/99 4:00 PM	Mon 3/22/99 4:45 PM	Kevin Williams
Terri Joseph	y2kptest	Compag FC-01-00	267	3/23/99	PASS	Mon 3/22/99 4:45 PM	Tue 3/23/99 8:30 AM	Thomas Brooks
Cynthia C. Leggett	y2kptest	Compag FC-01-00	267	3/23/99	PASS	Mon 3/22/99 4:45 PM	Tue 3/23/99 8:30 AM	Jennifer Brown
Ada Nelson	y2kptest					Mon 3/22/99 4:45 PM	Tue 3/23/99 8:30 AM	Kevin Williams
Karyn Pincus	y2kptest	System Soft 1.01.25	268	3/23/99	PASS	Tue 3/23/99 8:30 AM	Tue 3/23/99 9:15 AM	Thomas Brooks
Robert Racer	y2kptest	Compag FC-01-00	266	3/24/99	PASS	Tue 3/23/99 8:30 AM	Tue 3/23/99 9:15 AM	Jennifer Brown

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Docket No
98-N-1265

To: Betty Hiner@DFSR@FDAORAHQ
Cc:
Bcc:
From: "bogey" <bogey@htn.net>
Subject: Opposition to Draft M.O.U.
Date: Saturday, April 3, 1999 at 3:50:46 pm EST
Attach:
Certify: N

This is a multi-part message in MIME format.

-----= NextPart_000_0060_01BE7DE9.BCD9E0C0
Content-Type: multipart/alternative;
boundary="-----= NextPart_001_0061_01BE7DE9.BCD9E0C0"

-----= NextPart_001_0061_01BE7DE9.BCD9E0C0
Content-Type: text/plain;
charset="iso-8859-1"
Content-Transfer-Encoding: quoted-printable

I OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular, I =
OBJECT to the definition of "inordinate amount" which restricts the =
availability and the right to obtain medically necessary compounded =
medications by limiting the number of prescriptions that can be shipped =
across state lines from specialized compounding pharmacies.

Betty Grogg

April 3, 1999 =20

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COMMENTS: I've been taking compounded =
progesterone for over two years, which is not available in my county, or =
for that matter in my state. I do not want to take synthetic progestin, =
as it does not agree with me and does not accomplish the intended =
purpose. It is extremely difficult to find a medical doctor who is =
willing to take seriously the many hormonal problems women face as well =
as how it affects other medical problems, such as PMS, osteoporosis, =
heart health, etc., but to locate a pharmacy is even more difficult. I =
object to the government making these decisions for women.

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charset="iso-8859-1"
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